The Research Application Process

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Research Application Process

- CID Research Resources
- Requirements for research submission
- Research review categories

CID Research Resources

- NMCP IRB SOP
- Research application forms
- Informed consent form and procedures

CID Research Resources

- Scientific reviewer checklist
- IRB reviewer checklist
- CITI research ethics training
- cv template

CID Research Resources

- Vulnerable Populations Checklists
  - Pregnant Women
  - Children
- Wavier of Informed Consent
- Waiver of HIPAA Authorization

Research Requirements

- Current, dated curriculum vitae (cv)
- CITI – Research Ethics Training
- Electronic application form
  - Protocol number NMCP.2012.00__
  - Expiration date 2012
- Signature copy
  - Signature pages only
  - Scan or fax
  - No mail or Fed Ex

Participation

- Principal Investigator (PI)
  - Military, Federal employee
  - Only one PI
- Associate Investigator (AI)
- Sub-Investigator (SI)

Categories of Human Research Based Upon Risk to Subjects

- Case Studies
- Exempt research
- Expedited review
- Full Board review

Case Studies – Not Research

- An interesting case
- Organized observation, collection of data, the beginnings of research.
- One or two cases Not considered research
- Is not reported to the IRB
- Advise obtaining patient consent

Case Studies - Research

- Three or more cases – Case Series
- IRB review
- Contact CID for application forms
  - Prior to collecting the data
- Data collected prior to IRB approval may not be published

Exempt and Expedited Research

Exempt	Expedited
Minimal Risk	Minimal Risk
Research plan	Research plan
Scientific review	Scientific review
Chair approval	Chair approval
Annual review	Annual review

Exempt and Expedited Research

Exempt	Expedited
Retrospective only	Retrospective & Prospective
No list	Temporary list
Waiver of HIPAA	Waiver of HIPAA
NA	Waiver of Consent

Research considered exempt, 32 CFR 219.101

- Research involving the use of educational tests for example, aptitude and achievement tests; or surveys or interviews, are considered Exempt.

- Exceptions
  - a. Information obtained may not be recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects

  - b. Research may not be exempt IF: Any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects‘ financial standing, employability, or reputation

Research is considered exempt

- … if the information is recorded by the investigator in such a manner that **subjects cannot be identified, directly or through identifiers** linked to the subjects.

  - Data collection Sheet – must have no patient identifiers, no combination of data that could be used to identify
  - No combination that could be used to identify e.g. 23 yo mother of triplets, gave birth on 10 August, 2008
  - **Means no List – temporary or locked up**

Exempt Research, Examples

- Retrospective chart reviews
- Some surveys with no links to subjects
- Psychological and physiological effect of mild to moderate sleep loss.
- Psychological studies of learning, conditioning, sensory perception, personality, and group situations.
- Corrective therapeutic exercise.

Expedited Review

- Minimal risk
- Specific categories listed in the Federal Register
- May not be used where identification of the subjects would place them at risk of criminal or civil liability, or be damaging to their financial standing, employability,…
  - Includes unintentional identification
- Temporary list / destroy at end of study
- Informed consent required – a waiver may be requested

- Collection of data through noninvasive procedures routinely employed in clinical practice,
  (not involving general anesthesia or sedation)
- Weighing or testing sensory acuity. Magnetic resonance imaging.

- Ultrasound, electrocardiography,

- Moderate exercise, strength testing, body composition assessment, flexibility testing

- Collection of data, records, or specimens that have been collected solely for non-research purposes such as medical treatment or diagnosis
- Retrospective and prospective records review, permitting the use of a list of identifiers.
- List must be kept secure and private. Should be destroyed at end of study

Full Board Review

- Research that is greater than minimal risk
- Requires informed consent
- Literature search
- Forms:

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Full Board Review

- Invasive procedures
- Comparison of surgical procedures such as full incision vs endoscopy
- Psychological studies of hypnosis
- Exercise and fitness testing with extreme loads
- Pharmacological studies
- Live virus studies or testing of vaccines

Application Process

- PI: Talk with department Research Coordinator, discuss plans, determine if department will support your type of research
- Complete form, Research Coordinator review
- Return electronic copy to Portsmouth CID
- CID
  - Assigns tracking number
  - Advises PI on missing items
  - Sends e copy to scientific reviewers
  - Collaboration encouraged – needs an

Application Process

- Scientific reviewers return comments, Investigator revises
- Complete application will be scheduled for IRB review
- PI can attend IRB meeting via teleconference

Application Process

- IRB may require or recommend changes
- PI revises, IRB approves
- Agreements Verified as Completed
- Final approval by the Commander
- Upon approval by CO, PI will be notified to begin research
- The official consent form will be sent by email
- An official letter of approval will be sent later

Questions
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